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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590

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GLAXOSMITHKLINE  
Corporate Intellectual Property - UW2220  
P.O. Box 1539  
King of Prussia, PA 19406-0939

EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

18

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/060,849

Applicant(s)

MCALLISTER ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9                      6) ☐ Other:

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## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's election, amendment, and information disclosure statement, all received on 28 May 2003.

### ***Claim Objections***

Claim 38 is objected to because of the following informalities: It appears as if SDS, previously categorized as a surfactant, is now labeled as a lubricant in the second line of the claim. Also, it is unclear what is precisely meant by the phrase "SDS or a present". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-37 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 31-37, it is not clear from the wording of the claims whether the listed numbers are weight percentages. Furthermore, it is not clear whether a Markush group of compositions is being claimed. However, for the purpose of advancing prosecution, the claims will be treated as if a Markush group were being claimed in Claims 31-37.

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Regarding Claims 39-41, the preamble of the rejected claims must be drawn to a single element in order to particularly point out and distinctly define that which the applicants claim. The rejected claims are therefore in improper form. The examiner suggests an alternative phrasing of these claims, such as, "A composition according to Claim 1 that is in the form of a molded capsule shell, linker, or spacer."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatano *et al.* (U.S. Patent No. 6,309,666 B1) in view of Lehmann *et al.* (U.S. Patent No. 5,705,189)

The Hatano *et al.* patent teaches coated capsule compositions comprising a hard outer shell (See Abstract). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (See Column 5, Line 42 to Column 6, Line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include lactose and starch. Binders include ethylcellulose, HPMC, and polyethylene glycol. Disintegrants include polyvinylpyrrolidone. Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene

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sorbitan monooleate, polyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (See Column 11, Line 52 to Column 12, Line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (See Column 13, Lines 3-5).

The Hatano *et al.* patent does not disclose a molding process for making the disclosed hard outer capsule shells.

The Lehmann *et al.* patent discloses processes for producing acrylic and/or methacrylic articles, such as capsules, by molding (See Column 2, Line 53 to Column 3, Line 32). The articles may have various excipients blended into the melt, such as plasticizers, fillers, and mold-release agents, such as glycerol monostearate (See Column 3, Line 62 to Column 4, Line 2).

One of ordinary skill in the art would be motivated to combine the disclosures of Hatano *et al.* and Lehmann *et al.*, in order to produce, with a reasonable expectation of success, a molded capsule shell possessing certain desired characteristics, as imparted by the excipients disclosed in both Hatano *et al.* and Lehmann *et al.* Although certain excipients are not explicitly disclosed by the prior art, it is the position of the examiner that the particular selection of a specific component out of a broader class of excipients is not patentable without a showing by the applicant of its criticality. Although specific weight percentages of each component are not explicitly disclosed by the prior art, the examiner does not find the applicant's claims patentable absent a showing by the applicant of its criticality. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Thus, the instantly claimed invention is *prima facie* obvious.

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*Correspondence*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
August 11, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600